

MUSCULOSKELETAL DISORDERS: PREVENTION AND TREATMENT

Release Date: October 22, 2001

RFA: RFA-OH-02-004

National Institute for Occupational Safety and Health, (NIOSH)

National Institute of Arthritis and Musculoskeletal and Skin Diseases,(NIAMS)

Letter of Intent Receipt Date: December 4, 2001

Application Receipt Date: January 15, 2002

THIS RFA USES "MODULAR GRANT" AND "JUST-IN-TIME" CONCEPTS. MODULAR INSTRUCTIONS MUST BE USED FOR RESEARCH GRANT APPLICATIONS REQUESTING LESS THAN \$250,000 PER YEAR IN ALL YEARS. MODULAR BUDGET INSTRUCTIONS ARE PROVIDED IN SECTION C OF THE PHS 398 (REVISION 5/2001) AVAILABLE AT <http://grants.nih.gov/grants/funding/phs398/phs398.html>.

PURPOSE

This initiative marks the continued collaborative efforts of the National Institute of Occupational Safety and Health (NIOSH) and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) to support research focused on the prevention and treatment of musculoskeletal disorders (MSDs). The intent of this Request for Applications (RFA) is to support research in the areas of health and hazard surveillance, basic etiologic and medical evaluation, biomechanical and mechanobiological studies, diagnosis and treatment of MSDs, and the development and evaluation of new and existing interventions aimed at prevention. In particular, applications are solicited that are aimed at research topics involving the highest levels of risk, the most severe exposures, those with the most frequent occurrence, or those with the greatest opportunity for prevention or treatment of MSDs.

The research needs identified in this announcement are consistent with the National Occupational Research Agenda (NORA) developed by NIOSH and partners in the public and private sectors to provide a framework to guide occupational safety and health research in the new millennium towards topics which are most pressing and most likely to yield gains to the worker and the nation. The agenda identifies 21 research priorities. NORA priorities with specific

relevance to this announcement are: traumatic injuries; intervention effectiveness research; and control technology and personal protective equipment. Information about NORA is available through the NIOSH Home Page; <http://www.cdc.gov/niosh/norhmpg.html>. You may also refer to <http://www.cdc.gov/funding.htm>.

HEALTHY PEOPLE 2010

CDC and the NIH are committed to achieving the health promotion and disease prevention objectives of Healthy People 2010, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the focus area of Occupational Safety and Health. For a copy of "Healthy People 2010" (Full Report: Stock No. 017-001-00547-9), write or call: Superintendent of Documents, Government Printing Office, Washington D.C. 20402-9325, telephone (202) 512-1800 or visit the internet site: <http://www.health.gov/healthypeople/>.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, public and private nonprofit and for-profit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit and for-profit organizations, State and local governments or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau, federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations, and small, minority, and women-owned businesses that meet the above criteria. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

MECHANISM OF SUPPORT

The mechanism of support will be the individual research project grant (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant.

The total requested project period for an application submitted in response to this RFA may not exceed four years. Foreign grants are limited to 3 years. This RFA is a one-time solicitation.

FUNDS AVAILABLE

The National Institute of Occupational Safety and Health (NIOSH) intends to commit approximately \$1.0 million total direct costs in FY 2002 to fund up to 5 new grants and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) intends to commit approximately \$1.0 million total direct costs in FY 2003 to fund up to 5 new grants in response to this RFA. The maximum amount that may be requested is \$250,000 direct cost per year for laboratory-based studies and \$500,000 direct cost for population-based studies. Although the financial plans of the NIOSH and NIAMS provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

Awards will be made for a 12-month budget period within a project period up to four years. Continuation awards within the project period will be made on the basis of satisfactory progress and availability of funds in future years.

Use of Funds

Applicants should include in their budgets funds for one trip per year for an annual meeting of grantees to be held in Washington, D.C. The purpose of this meeting is to provide an opportunity for the exchange and dissemination of scientific information.

RESEARCH OBJECTIVES

Background

Musculoskeletal disorders (MSDs) involving the upper extremities, lower extremities and the back are an important national health problem. MSDs are one of the leading categories of injuries and illnesses in the work place, resulting in high levels of pain, discomfort, lost work time, and disability. MSDs account for the largest fraction of temporary and permanent disability, and as the population ages and physical capabilities decline, more Americans will develop MSDs than ever before. Many will require extensive adaptation of their work and home environment in order to maintain full functional capability. Additionally, compensation costs for disability are also likely to continue to increase. Fortunately, interventions have been shown to be effective in eliminating

or reducing the frequency and severity of these disorders, and treatments have been shown to be effective in improving functional ability for injured individuals. Additional research is needed, however, to increase the effectiveness of these prevention and treatment methods.

National Institute for Occupational Safety and Health, National Occupational Research Agenda for Musculoskeletal Disorders: Research Topics for the Next Decade, DHHS (NIOSH) publication number 2001-117, NIOSH, Cincinnati, Ohio 45226.

National Research Council and Institute of Medicine, Musculoskeletal Disorders and the Workplace: Low Back and Upper Extremities, National Academy Press, Washington, D.C.

Objectives

Applications are requested from any discipline to examine a wide range of factors in a variety of settings. The study of the combined or interactive effects of physical and non-physical factors is of special interest. This RFA is requesting proposals to conduct studies aimed at the ongoing systematic collection, analysis, interpretation, and dissemination of MSD health and hazard information in order to identify trends, develop prevention strategies, and evaluate the effectiveness of those strategies. Examples of topic areas of interest include, but are not limited to:

Epidemiological Research - Studies designed to improve epidemiologic research tools and studies examining the dose-response relationship between exposure to risk factors and the health outcomes are needed. Specific topics include:

- o Quantifying the relationship between exposures and MSD outcomes in both cross-sectional and prospective study designs
- o Development of improved tools for measuring exposures (dose) and health outcomes (response), such as force, posture, motion, and vibration; tools should be practical, consistent, precise, accurate, and easy to use.
- o Development/refinement of epidemiologic tools with adequate sensitivity and specificity for epidemiologic study in work and non-work environments. Studies should address tools or criteria that focus on physical examination and sensory discrimination criteria to identify MSD outcomes, epidemiologic case definitions for MSDs, standardized survey instruments to identify symptomatic

MSD outcomes, and physiological measures appropriate for measuring relevant features of MSDs.

Etiological and Medical Research - Research is needed to better describe the relationship between exposure to risk factors, both singly and in combination, and the development of disease and disability. Specific examples of topics of interest include:

- o Refining instruments to detect and quantify the contribution of risk factors to the disease process.
- o Studies aimed at clearly defining stages of the MSD process and delineating the natural history of MSD (pathogenesis and recovery).
- o Studies focusing on clarifying the interaction of factors at different stages of causation, development, and treatment of MSD and measurement of those risk factors.
- o Investigations focusing on determining the impact of personal factors on risk of MSD, including studies investigating the relative effects of differences in age, gender, physical conditioning, biological characteristics, cultural differences, diurnal variations, genetics, and history of previous injury/illnesses (acute, cumulative, or chronic) is needed.

Psychosocial and Work Organization Research - Studies aimed at determining the effects of psychological, psychosocial, and work organizational factors on the occurrence of MSD are needed. Specifically, investigations are needed to determine the mechanisms through which psychosocial and work organizational stressors contribute to or impact development of MSDs. Specific examples of topics of interest include studies directed at determining the effects of the following factors on development of MSDs:

- o Stressful working conditions, such as hectic or routine tasks and unrealistic deadlines.
- o Individual and situational non-work factors, such as balance between work and family or personal life, social support network, personality, and coping skills.
- o Poor interpersonal relationships, indefinite work roles, and lack of worker involvement in decision making.
- o Work schedules, including extended hours of work, shift work, and mandatory overtime.

- o Specific types of work, such as paced work, piecework, and teamwork.
- o Non-stereotypical work arrangements and management style, such as telecommuting, temporary work assignments, and other supervisory or management staffing arrangements.
- o Down-sizing and labor surpluses and shortages

Biomechanical and Mechanobiology Research - Laboratory and field studies examining the impact of biomechanical risk factors including exposures to excessive force, awkward posture, rapid movement, and vibration in human and animal studies. These can be characterized in terms of their magnitude and temporal factors, such as frequency, repetition, duty cycle, and duration of exposure. Specific topics of interest include:

- o Characterizing ultrastructural and cellular responses to cyclical physical loading exposure for vertebrae/disc, upper extremity tendon and muscle, articular cartilage, and peripheral nerve using in vivo animal models.
- o Investigating how risk factors affect tissue loading patterns and tolerance limits for joints and soft tissues in humans, including quantifying the relationship between loading and the pain process, as well as exploring the influence of psychological stress on the function of the musculoskeletal system and the resulting mechanical loading of the joints.

Intervention Research - Research is also needed to develop and evaluate new and existing intervention strategies for preventing or reducing the incidence, severity, and disability associated with MSDs. A large amount of research has been conducted over the past few decades, but because of the wide variability between individuals and the complexity of causal and contextual factors and their interactions, there is a need for more research to evaluate which interventions are the most effective. Because intervention research is difficult to conduct and adequate comparison controls are often not available, very large sample sizes may be needed to show that an intervention is effective in reducing health outcomes. Therefore, studies aimed at demonstrating reduced exposure may be equally useful in evaluating the effectiveness of interventions. Specific examples of topics of interest include:

- o Determining the effectiveness of alternative (product and/or tool) design criteria (force, spatial requirements of work).

- o Determining the effectiveness of reducing or optimizing the mechanical work demands (force, movement, and posture) and temporal patterns of exposure.
- o Determining the effectiveness of training and education programs.
- o Determining the effectiveness of exercise and stretching programs.
- o Development and evaluation of methods for determining the costs and benefits of ergonomic interventions.
- o Determining the effectiveness of worker selection/placement and job assignment on prevention of MSDs.
- o Determining the effectiveness of emerging prevention technologies.
- o Conducting rigorous evaluation of workplace interventions including but not limited to randomized controlled trials or other scientifically valid approaches.
- o Promoting investigation of multifactorial interventions.

Special Populations - Studies focusing on the impact of MSDs on selected sub-groups of the population are needed, such as children, older individuals, minorities, women, and other understudied populations. Examples of specific topics of interest include:

- o Identify and evaluate unique MSD risks for children and women.
- o Evaluate how changes in tolerance due to aging impacts upon risk for MSDs.
- o Determine the impact of aging on the healing and recovery process.
- o Collect anthropometric and work capacity data for older individuals to determine how anthropometric variables change with age.
- o Evaluate whether individuals with pre-existing conditions, such as diabetes, cancer, neurological disorders, etc., are at increased risk for development of MSDs.

- o Evaluate the impact of occupational and non-occupational exposures to children on future development of MSDs.

Diagnosis and Treatment - Research efforts are needed to improve and standardize methods of identification and evaluation of MSD outcomes. Studies aimed at evaluating the efficacy of various forms of treatment are needed. Specific topics of interest include:

- o Develop standard definitions for work-related MSD, risk factors, and for terms, such as discomfort, pain, injury, disease, disability, and recovery. Establish endpoints that are clear, definitive, valid, and reliable.
- o Development of precise diagnostic tools that are effective in early identification of MSDs.
- o Development of guidelines for effective treatment and return to work.
- o Establish approved methods and objective tests to diagnose and evaluate whether an injury is physical, psychological, or psychosocial.
- o Standardize diagnostic physical examinations.
- o Evaluate available high-technology imaging tools, such as microsensors and magnetic resonance imaging (MRI), for the diagnosis of MSD, and design new diagnostic tools specifically for musculoskeletal injury research.
- o Develop and validate biochemical markers to identify injured individuals
- o Conduct research (clinical trials) to evaluate the efficacy of various forms of treatment for MSD, including surgery and rehabilitation. Evaluate the impact of workers compensation and disability benefit availability and other factors on treatment and outcome.

Useful References

National Institute for Occupational Safety and Health. Musculoskeletal Disorders and Workplace Factors. A Critical Review of Epidemiological Evidence for Work-Related Musculoskeletal Disorders of the Neck, Upper Extremities, and Low Back. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute

for Occupational Safety and Health, DHHS (NIOSH) Publication No.97-141
(<http://www.cdc.gov/niosh/nora.html>).

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the CDC and the NIH to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC and NIH-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, pages 47947-47951, and dated Friday, September 15, 1995.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," published in the NIH Guide for Grants and Contracts on August 2, 2000

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html>);

a complete copy of the updated Guidelines are available at

http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of CDC and the NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998. This policy will be followed by NIOSH for this announcement.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address:

<http://grants.nih.gov/grants/funding/children/children.htm>.

Investigators also may obtain copies of these policies from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

HUMAN SUBJECTS REQUIREMENTS

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services (DHHS) Regulations (Title 45 Code of Federal Regulations Part 46) regarding the protection of human research subjects. All awardees of CDC grants and cooperative agreements and their performance sites engaged in human subjects research must file an assurance of compliance with the regulations and have continuing reviews of the research protocol by appropriate institutional review boards.

In order to obtain a federal-wide Assurance (FWA) of Protection for Human Subjects, the applicant must complete an on-line application at the Office for Human Research Protections (OHRP) website or write to the OHRP for an application. OHRP will verify that the signatory official and the Human Subjects Protections Administrator have completed the OHRP Assurance Training/Education Module before approving the FWA. Existing Multiple Project Assurances (MPAs), Cooperative Project Assurances (CPAs), and Single Project Assurances (SPAs) remain in full effect until they expire or until December 31, 2003, whichever comes first.

To obtain a FWA contact the OHRP at:

<http://ohrp.osophs.dhhs.gov/irbasur.htm> or write to:

Office for Human Research Protections (OHRP)
Department of Health and Human Services
6100 Executive Boulevard, Suite 3B01, MSC 7501
Rockville, Maryland 20892-7507
(Note: For Express or Hand Delivered Mail, Use Zip Code 20852)

Note: In addition to other applicable committees, Indian Health Service (IHS) institutional review committees must also review the project if any component of IHS will be involved with or will support the research. If any American Indian community is involved, its tribal government must also approve the applicable portion of that project.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000, at the following website: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

ANIMAL SUBJECTS REQUIREMENTS

If the proposed project involves research on animal subjects, compliance with the "PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions" is required. An applicant (as well as each subcontractor or cooperating institution that has immediate responsibility for animal subjects) proposing to use vertebrate animals in CDC-supported activities must file (or have on file) the Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health. The applicant must provide in the application the assurance of compliance number and evidence of review and approval (including the date of the most recent approval) by the Institutional Care and Use Committee (IACUC). Web page <http://grants.nih.gov/grants/olaw/references/phspol.htm>.

URLS IN NIOSH and NIH GRANT APPLICATIONS OR APPENDICES

All applications must be self-contained within specified page limitations. Unless otherwise specified, internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an internet site.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT

By regulation (45 CFR 74.36), grantees that are institutions of higher education, hospitals, or non-profit organizations are required to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances (OMB Circular A-110). Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. For further information on this policy refer to page 52 in the PHS 398 grant application or access the NIH Guide for Grants and Contracts Announcement at: http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

LETTER OF INTENT

Prospective applicants are asked to submit, by December 4, 2001, a letter of intent that includes the number and title of the RFA, a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, and the identities of other key personnel and participating institutions. Although a letter of intent is not required, is not binding, and is not used in the review of an application, the information that it contains is used to estimate the potential review workload and plan the review.

The letter of intent is to be submitted to:

Pervis C. Major, Ph.D.
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention (CDC)
1095 Willowdale Rd
Morgantown, WV 26505
Telephone: 304-285-5979
Fax: 304-285-6147
Email: pmajor@cdc.gov

APPLICATION PROCEDURES

The PHS 398 research grant application instructions and forms (rev. 5/2001) at <http://grants.nih.gov/grants/funding/phs398/phs398.pdf> must be used in applying for these grants. This version of PHS 398 is available in an interactive, searchable format. For further assistance contact GrantsInfo, Telephone 301/435-0714, Email: GrantsInfo@nih.gov.

SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS

The modular grant concept establishes specific modules in which direct costs may be requested as well as a maximum level for requested budgets. Only limited budgetary information is required under this approach. The just-in-time concept allows applicants to submit certain information only when there is a possibility for an award. It is anticipated that these changes will reduce the administrative burden for the applicants, reviewers and NIH staff. The research grant application form PHS 398 (rev. 5/2001) at <http://grants.nih.gov/grants/funding/phs398/phs398.html> is to be used in applying for these grants, with modular budget instructions provided in Section C of the application instructions.

The RFA label available in the PHS 398 (rev. 5/2001) application form (<http://grants.nih.gov/grants/funding/phs398/labels.pdf>) must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed photocopies, in one package to:

Center for Scientific Review (CSR)
National Institutes of Health
6701 Rockledge Drive, Room 1040 - MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application must also be sent to:

Pervis C. Major, Ph.D.
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention (CDC)
1095 Willowdale Rd
Morgantown, WV 26505
Telephone: 304-285-5979
Fax: 304-285-6147
Email: pmajor@cdc.gov

Applications must be received by January 15, 2002. If an application is received after that date, it will be returned to the applicant without review. CSR and NIOSH will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. CSR and NIOSH will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an application already reviewed, but such an application must follow the guidance in the PHS Form 398 application instructions for the preparation of revised applications, including an Introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by CSR and responsiveness by NIOSH. Applications determined to be incomplete or unresponsive to this RFA will be returned to the applicant without further consideration. Applications that are complete and responsive to the RFA will be reviewed for technical merit by a scientific review group convened by NIOSH.

All applications will be judged on the basis of the scientific merit of the proposed project and the documented ability of the investigators to meet the RESEARCH OBJECTIVES of the RFA. As part of the scientific merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score.

The criteria that NIOSH will use to review applications for scientific merit and for meeting program objectives are provided below.

Scientific Review Criteria

- o Significance - Does this study address an important problem related to the topical research issues outlined in this announcement? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

- o Approach - Are the conceptual framework, design (including composition of study population), methods, and analyses adequately developed, well-integrated and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

- o Innovation - Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?
- o Investigator - Is the investigator appropriately trained and well-suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers, if any?
- o Environment - Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there documentation of cooperation from industry, unions, communities, or other participants in the project, where applicable? Is there evidence of institutional support and availability of resources necessary to perform the project?
- o Adequacy of plans to include both genders, minorities and their subgroups, and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.
- o The adequacy of the proposed protection of humans, animals, or the environment, to the extent that they may be adversely affected by the project proposed in the application.
- o Availability of special opportunities for furthering research programs through the use of unusual talent resources, populations, or environmental conditions in other countries which are not readily available in the United States or which provide augmentation of existing U.S. resources.

Programmatic Review Criteria

- o Magnitude of the problem in terms of numbers of workers affected.
- o Severity of the disease or injury in the worker population.
- o Likelihood of developing applied technical knowledge for the prevention of occupational safety and health hazards on a national or regional basis.

SCHEDULE

Letter of Intent Receipt Date: December 4, 2001

Application Receipt Date: January 15, 2002

Earliest Anticipated Award Date: August 1, 2002 (NIOSH)/October 1, 2002 (NIAMS)

AWARD CONSIDERATIONS

Applications will be considered for award based upon (a) scientific merit, (b) program importance, (c) program balance of research areas, and (d) availability of funds.

INQUIRIES

Inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. This RFA and other CDC Announcements can be found on the CDC HomePage (<http://www.cdc.gov>) under the "Funding" section (see "Grants and Cooperative Agreements" scroll down to "Occupational Safety and Health"). This RFA can also be found on the NIOSH HomePage (<http://www.cdc.gov/niosh>) under "Extramural Programs", "Current Funding Opportunities" and on the NIAMS Homepage (<http://www.nih.gov/niams>) under "Grants & Contracts", "Requests for Applications", "Currently Active RFAs".

Direct inquiries regarding NIOSH programmatic issues to:

Michael Galvin, Ph.D.
Office of Extramural Programs
National Institute for Occupational Safety and Health
1600 Clifton Road, N.E.
Building 1, Room 3053, MS D-30
Atlanta, GA 30333
Telephone: (404) 639-3343
FAX: (404) 639-4616
Email: mgalvin@cdc.gov

Direct inquiries regarding NIAMS programmatic issues to:

James S. Panagis, MD, MPH
Director, Orthopaedics Program

National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-37K, MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-5055
FAX: (301) 480-4543
E-mail: jp149d@nih.gov

Direct inquiries regarding grants management business matters to:

Joanne Wojcik
Grants Management Branch
Procurement and Grants Office
CDC Announcement Number CDC 02015
Centers for Disease Control and Prevention
2920 Brandywine Road, Suite 3000
Atlanta, GA 30341-4146
Telephone: 770/488-2717
Email: jcw6@cdc.gov

Ms. Melinda Nelson
Grants Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-37K, MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-3535
FAX: (301) 480-5450
E-mail: mn23Z@nih.gov

AUTHORITY AND REGULATIONS

The Catalog of Federal Domestic Assistance number is: 93.262 for the National Institute for Occupational Safety and Health (NIOSH) and 93.846 for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). This program is authorized under the Public Health Service Act, as amended, Section 301(a) [42 U.S.C. 241(a)], and the Occupational Safety and Health Act of 1970, Section 20(a) [29 U.S.C. 669(a)]. The applicable program regulation is 42 CFR Part 52. This program is not subject to the intergovernmental review requirements of executive order 12372 or Health Systems Agency Review.

LOBBYING RESTRICTIONS

Applicants should be aware of restrictions on the use of Health and Human Services (HHS) funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352, recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, no part of the Center for Disease Control and Prevention (CDC) appropriated funds shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State or local legislature, except in presentation to the Congress or any State or local legislature itself. No part of the appropriated funds shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State or local legislature.

Any activity designed to influence action in regard to a particular piece of pending legislation would be considered "lobbying." That is lobbying for or against pending legislation, as well as indirect or "grass roots" lobbying efforts by award recipients that are directed at inducing members of the public to contact their elected representatives at the Federal or State levels to urge support of, or opposition to, pending legislative proposals is prohibited. As a matter of policy, CDC extends the prohibitions to lobbying with respect to local legislation and local legislative bodies.

The provisions are not intended to prohibit all interaction with the legislative branch, or to prohibit educational efforts pertaining to public health. Clearly there are circumstances when it is advisable and permissible to provide information to the legislative branch in order to foster implementation of prevention strategies to promote public health. However, it would not be permissible to influence, directly or indirectly, a specific piece of pending legislation.

It remains permissible to use CDC funds to engage in activity to enhance prevention; collect and analyze data; publish and disseminate results of research and surveillance data; implement

prevention strategies; conduct community outreach services; provide leadership and training; and foster safe and healthful environments.

Recipients of CDC grants and cooperative agreements need to be careful to prevent CDC funds from being used to influence or promote pending legislation. With respect to conferences, public events, publication, and "grassroots" activities that relate to specific legislation, recipients of CDC funds should give attention to isolating and separating the appropriate use of CDC funds from non-CDC funds. CDC also cautions recipients of CDC funds to be careful not to give the appearance that CDC funds are being used to carry out activities in a manner that is prohibited under Federal law.

SMOKE-FREE WORKPLACE

CDC strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

SMALL, MINORITY, AND WOMEN-OWNED BUSINESS

It is a national policy to place a fair share of purchases with small, minority and women-owned business firms. The Department of Health and Human Services is strongly committed to the objective of this policy and encourages all recipients of its grants and cooperative agreements to take affirmative steps to ensure such fairness. In particular, recipients should:

- o Place small, minority, women-owned business firms on bidders mailing lists.
- o Solicit these firms whenever they are potential sources of supplies, equipment, construction, or services.
- o Where feasible, divide total requirements into smaller needs, and set delivery schedules that will encourage participation by these firms.
- o Use the assistance of the Minority Business Development Agency of the Department of Commerce, the Office of Small and Disadvantaged Business Utilization, DHHS, and similar state and local offices.

RESEARCH INTEGRITY

The signature of the institution official on the face page of the application submitted under this Program Announcement is certifying compliance with the Department of Health and Human Services (DHHS) regulations in Title 42 Part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science." The regulation places several requirements on institutions receiving or applying for funds under the PHS Act that are monitored by the DHHS Office of Research Integrity's (ORI) Assurance Program.

For examples:

Section 50.103(a) of the regulation states: "Each institution that applies for or receives assistance under the Act for any project or program which involves the conduct of biomedical or behavioral research must have an assurance satisfactory to the Secretary (DHHS) that the applicant: (1) Has established an administrative process, that meets the requirements of this subpart, for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored biomedical and behavioral research conducted at the applicant institution or sponsored by the applicant; and (2) Will comply with its own administrative process and the requirements of this Subpart." Section 50.103(b) of the regulation states that: "an applicant or recipient institution shall make an annual submission to the [ORI] as follows: (1) The institution's assurance shall be submitted to the [ORI], on a form prescribed by the Secretary,...and updated annually thereafter...(2) An institution shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe."

[Return to Volume Index](#)

[Return to NIH Guide Main Index](#)